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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/500,700	02/09/2000	Carlos F. Barbas III	SCRIP1160-4	2975

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03/28/2002

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EXAMINER

LEFFERS JR, GERALD G

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 03/28/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/500,700

Applicant(s)

BARBAS III ET AL.

Examiner

Gerald G Leffers Jr.

Art Unit

1636

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 March 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 13 March 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: none.

Claim(s) objected to: none.

Claim(s) rejected: 2-5, 16-19, 40 and 42-46.

Claim(s) withdrawn from consideration: 47-50.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). 11 & 12.
10. ☐ Other: \_\_\_\_\_

*Remy Yucel*

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Continuation of 2. NOTE: the amendments to the claims raise new issues. For example, the limitation wherein the zinc-finger variant binds a polynucleotide sequence different from a sequence bound by a zinc finger-nucleotide binding polypeptide not having a modification changes the scope of the invention, raises new art issues and 112, 1st paragraph issues.

Continuation of 5. does NOT place the application in condition for allowance because: Applicants' arguments directed towards the claims as amended are moot because the amendment has not been entered into the record.

Arguments directed towards rejection of claims 42-46 under 112 1st paragraph for lack of written description are not persuasive. The response admits the rejected claims do encompass a large genus of zinc finger modules, but essentially argues that: 1) the teachings in the specification and in the art provide numerous zinc finger proteins from which to select zinc finger modules for generating a hybrid zinc finger protein as claimed in the present invention, 2) the specification clearly teaches one of skill in the art how to screen for zinc finger proteins encompassed by the rejected claims, 3) the specification teaches that variant/hybrid zinc finger proteins of the invention are useful for suppressing or inducing gene expression, 4) one of skill in the art can use standard gene expression assays to determine whether a particular variant/hybrid zinc finger protein exhibits an effect on expression of a particular gene of interest, 5) the specification teaches "A variant may be a hybrid which contains zinc finger domain(s) from one protein linked to zinc finger domain(s) of a second protein, for example." (page 10, lines 15-25).

While it is true that the specification describes the barest outline of what the zinc finger variants of the invention may look like (i.e. one zinc finger domain linked to another), and while it is true that there are a number of zinc finger proteins known in the art at the time of applicants' invention, there does not appear to be in the specification as filed or prior art a sufficient description to enable one of skill in the art to envision a sufficient number of specific embodiments sufficient to describe the entire, broadly claimed genus of such proteins. For example, how are the domains to be linked? What amino acid residues are going to be present to be acceptable for use in linking the different finger domains. What are the amino acid sequences going to be within the zinc-finger domains that are critical for contacting specific nucleotides in the DNA-binding site? What is the percentage of possible zinc-finger proteins out there in nature from any source that have actually been described? What nucleic acid sequences will the hybrid zinc finger proteins bind? The specification and prior art do not provide sufficient basis for one of skill in the art to answer these questions pertaining to the structure and function of the claimed polypeptides such that the entire, broadly claimed genus is described. Arguments directed towards screening methods and standard expression techniques are more suited to an enablement rejection and are not relevant with regard to description of the claimed invention..

  
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